

Rhode Island State Supplied Vaccines (SSV) Program Financial Restitution Policy



The Financial Restitution Policy was developed in accordance with Rhode Island's State Supplied Vaccines Program for the purpose of replacing vaccine wasted or spoiled due to negligence and/or failure to properly store, handle, or rotate vaccine inventory.

Definitions

- Wasted:** Any vaccine that cannot be used. This includes expired, spoiled, lost, or excess vaccines.
- Expired:** Any vaccine with an expiration date that has passed.
- Spoiled:** Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the vaccine manufacturer before determining that the vaccine is non-viable.
- Lost:** Any vaccine ordered but not delivered (or not delivered in a timely manner) by the shipping company resulting in lost and/or spoiled vaccine.
- Excess:** Vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

Situations Requiring Financial Restitution

The following situations are examples of negligence that may require financial restitution. This list is not exhaustive:

- Failure to rotate or transfer vaccine that results in expired vaccine
- Drawing up vaccine prior to patient screening.
- Handling and storage mistakes by provider staff
- Vaccine that is left out of the refrigeration unit and becomes non-viable.
- Freezing vaccine meant to be refrigerated
- Refrigerating vaccine meant to be frozen
- Refrigerator left unplugged or electrical breaker switched off
- Refrigerator door left open or ajar by provider staff, contractors, or guests
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the Immunization Program within 30 days from the date the problem is identified
- Any power outages in which provider fails to act according to the Practice's ***Vaccine Disaster Recovery Plan***
- Situations in which health care providers must re-vaccinate due to failure to keep vaccine viable (temperatures out of acceptable range) or improper administration. Provider will be responsible for the cost of vaccine for re-vaccination.
- Ordering habits resulting in overstock that lead to expiration of vaccines (i.e. maintaining an inventory of more than 90-days supply)

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Examples of Situations Not Requiring Financial Restitution

The following examples are situations considered to be out of the providers' control, and generally do not require financial restitution. This list is not exhaustive. Providers should always contact the manufacturer for a determination regarding the viability of suspect vaccine.

- Package is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit
- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider
- A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, but power is lost at that location
- Partially used multi-dose vials
- A vial that is accidentally dropped or broken by provider
- Expired vaccine that the provider attempted to redistribute 120-days or more prior to expiration but was unsuccessful.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Program within 30 days from the date you become aware of the situation
- Extraordinary situations not listed above which are deemed by the Immunization Program to be beyond the provider's control (when reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the practice's Disaster Recovery Plan)

Annual Wastage Allowance

Practices will be allowed a 5% allowance towards wasted vaccine. The allowance will be based on the total cost of vaccines wasted as compared to the total cost of vaccines ordered over the previous 12-month period for the practice.

- Once a practice has used the 5% allowance they will need to achieve 12 consecutive months without incident before another 5% allowance will be made available to the practice.
 - Example - a delivery of vaccine is left out containing vaccine worth \$15,000. The practice has ordered \$100,000 worth of inventory over the past 12-months; therefore the practice would owe \$10,000 in restitution (\$5,000 waived for allowance). However, any additional events over the next 12-months would require 100% restitution, since the 5% allowance has already been met in the first incident.

Procedure for Financial Restitution

This policy applies to any vaccine reported to the Immunization Program as wasted on or after October 1, 2008.

- Each incident reported will be reviewed on a case-by-case basis by the Immunization Policy Committee to determine whether restitution will be required or if extenuating circumstances prevail.
- If the practice is found to be at fault the practice will receive an invoice for vaccine reported as wasted to the Immunization Program from the Department of Health (HEALTH).

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- The invoice will reflect the current replacement cost of the vaccine, minus the excise tax. Reimbursement for the cost of vaccine wasted shall be due 30 days from the date of the invoice.
- A late penalty of 10 percent may be charged on past due accounts.
- Failure to pay any outstanding penalties will result in a delay or forfeiture of future program enrollment for the practice.

Procedure for Returning Vaccine

- Call the vaccine manufacturer as soon as you suspect vaccine may be spoiled and prior to returning any vaccine for viability status
- Complete and fax a copy of the *Vaccine Return and Emergency Response Worksheet* to the Immunization Program for a return merchandise authorization (RMA)
- Return all open and unopened vials/pre-filled syringes of spoiled or expired vaccine with a copy of the RMA to the distributor, regardless of any financial restitution status applied to the vaccine
- Never return needles to the distributor

Procedure for Appeal Process

The Financial Restitution Policy allows for an appeal process. If your practice/clinic experiences a wastage situation which is defined as provider negligence, and you believe there are circumstances which prove it is not negligence, you may appeal **after** you receive the invoice.

This appeal must be in writing and can be submitted by mail or fax on your letterhead or on a “Financial Restitution Appeal” form. If you choose not to use the Financial Restitution Appeal Form, you must include the same information as that contained on the form. It is very important that any information that you would like considered in your appeal (e.g. repair invoices) be included with the appeal form.

Fax to: (401) 222-3805
Attention: Vaccine Manager

Mail to: RI Department of Health
Immunization Program
Attention: Vaccine Manager
3 Capitol Hill – Room 302
Providence, RI 02908

- Each appeal will be considered on a case-by-case basis
- Your office will receive written notification regarding the outcome of your appeal within 30 days of receipt
- The practice lead physician/medical director must sign your appeal

If you have any questions concerning this policy, please call the Vaccine Manager at (401) 222-5988 for assistance.

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Financial Restitution Appeal Form

**Fax to: Vaccine Manager
(401) 222-3805**

Facility Name: _____
Contact: _____
SSV Pin: _____
Address: _____

Restitution Invoice Number: _____

The vaccine in question was returned on: _____
(Attach a copy of the return authorization)

We believe we should not be held financially responsible for the vaccine and request reconsideration for the following reason(s). Below is a detailed explanation of the circumstances surrounding the events with attachments as needed.

(Signature and date)

(Printed Name & License # of Medical Director/Lead Physician)

For Program Use Only:

Decision rendered on: _____ By: _____

☐ Responsible ☐ Not Responsible

Date Notified: _____